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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,092	10/13/2005	Naoki Kimura	TOYA115.015APC	9129

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EXAMINER	
BHAT, NARAYAN KAMESHWAR	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
06/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/553,092	KIMURA ET AL.	
	Examiner	Art Unit	
	Narayan K. Bhat	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/2005; 6/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed on October 13, 2005. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Claims 1-12 are pending in the application.

Election/Restrictions

3. Applicant's election with traverse of group I invention in the reply filed on March 21, 2007 is acknowledged. Since the applicant didn't provide any grounds for the traversal, the restriction requirement is still deemed proper and is therefore made FINAL.

4. Claim 12 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 21, 2007 is acknowledged.

6. Claims 1-11 are under prosecution.

Claim Objections

7. Claim 5 is objected to because of the following informalities because it does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 is rejected over the recitation of "immobilized on the core particle by a chemical bond" in line 3 and is confusing because it is not clear what must be immobilized by a chemical bond, the organic compound or the biological active substance.

11. Claims 2-11 are rejected because they are dependent on claim 1.

12. Claim 5 is rejected because the claim suggests that the core particle, base particle and device all have a diameter, yet there is no requirement previously that they be round.

13. Claim 5 is rejected because the equations appear to be based on multiple base particles but claim 1 requires only single base particle.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 4-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Takenishi et al (USPN 6,017,742 issued January 25, 2000).

Regarding claim 1, Takenishi et al teaches a carrier, i.e., core particle (Column 2, line 48) and an organic compound, i.e., carbodiimide containing polymer, supported on a carrier (Column 2, line 49) reacting with biologically active substance via carbodiimide group, thus immobilizing biologically active substance on to the carrier (Column 2, lines 50-56).

Takenishi et al also teaches that carbodiimide polymer contains 2-100 carbodiimide groups (Column 4, line 53) and is water soluble (Column 5, line 52) and the carbodiimide group is hydrophilic as defined in the instant specification (See instant specification, Paragraph 0032-0033) thus meeting the limitation of the instant claim, that is, organic compound having two or more hydrophilic groups. Takenishi et al further teaches that carbodiimide polymer has high adhesivity to the carrier thus able to immobilize on to the carrier (Column 5, lines 25-40). Since the adhesion involves both

covalent and non covalent bonding and the later include ionic, nonionic and coordinate bonds. Since the instant specification defines ionic or coordinated bonds as chemical bonds (See instant specification, Paragraph 0050), teachings of Takenish et al encompass binding of carbodiimide to the carrier is by chemical bonding. Takenishi et al also teaches carbodiimide group reacts with biologically active substance via chemical bonding (Column 6, lines 1-2) thus immobilizing biologically active substance on to the carrier (Column 5, lines 41-49). Takenishi et al also teaches that carbodiimide group can form a covalent bond reacting with all active hydrogen groups (Column 5, lines 8-19) that includes the free amino groups on the proteins, thus also teaching immobilization of biologically active substance by a chemical bond. The carrier and biologically active substance immobilized on the carrier of Takenishi et al are the core and the base particle (herein after will be referred to as base particle) of the instant claim. The teachings of Takenishi et al thus anticipate claim 1.

Regarding claim 4, Takenishi et al teaches that the base particle is on a bead, which by inherency is of substantially spherical shape (Column 10, See example 6).

Regarding claim 5, the claim is indefinite, as written but appears to imply further define the claimed invention by a particular property. Since Takenishi et al teach a device, i.e., base particle, which meets the structural limits of the claims and the examiner does not have the benefit of a laboratory to measure the property of a

disclosed device, this claim is rejected, as it appears this property would be inherent feature of the disclosed device.

Regarding claim 6, Takenishi et al teaches that the carrier and the biologically active substance are bonded by a reaction with a functional group selected from the group consisting of carbodiimide group, that is, carbodiimide polymer (Column 5, lines 33-49).

Regarding claims 7 and 11, Takenishi et al teach the organic compound is a carbodiimide polymer represented by the following formula: Ax--(R--X)n--R--Ay wherein Ax and Ay are carbodiimide groups which are hydrophilic segment having functional group that exhibits hydrophilicityas defined in the instant specification (See instant specification, Paragraph 0032-0033) and n is an integer of 2 to 100 (Column 4, lines 52-64).

Regarding claim 8, Takenishi et al teaches that the biologically active substance is nucleic acids and protein (Column 5, lines 41-49).

Regarding claim 9, Takenishi et al teaches that the base particle device for detecting DNA that is, a second biologically active substance contained in a sample by using a specific bond of the biologically active substance and the second biologically active substance in the sample (Column 8, lines 45-67).

Regarding claim 10, Takenishi et al teaches the biologically active substance is an antibody that can be configured for its intended use as an agent for therapeutic treatment of a disease (Column 5, lines 56-65).

16. Claims 1-6, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al (USPN 5,955,108 issued September 21, 1999).

Regarding claim 1, Sutton et al teaches microparticle (Column 5, line 7) and an organic carbodiimide compound, i.e., EDCI (Column 5, line 11), which is a hetero bifunctional cross linker and is water soluble and by inherency has two reactive hydrogen group that can link directly, i.e., covalently with amine functional group on the microparticle (Column 3, lines 1-9) and thus immobilizing on to the microparticle. Since the covalent bonding is defined as chemical bond in the instant specification (See instant specification, Paragraph 0050), teaching of Sutton et al encompass binding of carbodiimide to the microparicle is by chemical bonding. The microparticle of Sutton et al is the core particle of the instant claim.

Sutton et al further teaches the conjugation of proteins or drugs to microparticles using EDCI (Column 5, lines 7-13), which is a hetero bifunctional cross linker and is water soluble and by inherency has two reactive hydrogen group that can covalently attach protein and drugs to microparticle (Column 6, line 19). Sutton et al refers the microparticle attached with biomolecules as microcapsules and they are base particles of the instant claim. The teachings of Sutton et al thus encompass a biologically active substance that is protein, bonded to the base particle via the organic compound.

Regarding claim 2, Sutton et al teaches that microcapsule, i.e., base particle monodispersed in an aqueous medium (Column 5, line 21).

Regarding claim 3, Sutton et al teaches that microcapsule, i.e., the base particle has an average particle diameter of 3 to 3.8 micrometer (Column 11, line 24).

Regarding claim 4, Sutton et al teaches that the base particle, human serum albumin microsphere carrier (Column 13, lines 6-11).

Regarding claim 5, Sutton et al teaches HAS microcapsules, i.e., base particles with a mean size of 3.28 +- 0.6 micrometers with 90% of the mass within the 2 to 5 micrometer range (Column 6 & 7, lines 64-67 & 11-24) thus teaching the relatively even particle size as also contemplated in the instant specification (See instant specification, Paragraph 0142).

The claim 5 is also indefinite, as written but appears to imply further define the claimed invention by a particular property. Since Sutton et al teach a device, i.e., base particle, which meets the structural limits of the claims and the examiner does not have the benefit of a laboratory to measure the property of a disclosed device, this claim is rejected, as it appears this property would be inherent feature of the disclosed device.

Regarding claim 6, Sutton et al teaches that the microparticle and the biologically active substance are bonded by a reaction with a functional group selected from the group consisting of carbodiimide group, that is, EDCI (Column 5, line 12).

Regarding claim 8, Sutton et al teaches that the biologically active substance is protein (Column 5, line 8).

Regarding claim 9, Sutton et al teaches that the microcapsule device can be used for its intended use, i.e., detecting platelet activation (Column 9, lines 15-26), that is, a second biologically active substance contained in a sample by using a specific bond of the biologically active substance and the second biologically active substance in the sample.

Regarding claim 10, Sutton et al teaches cisplatin, the biologically active substance is an agent for therapeutic treatment of a disease (Column 6, lines 19-28).

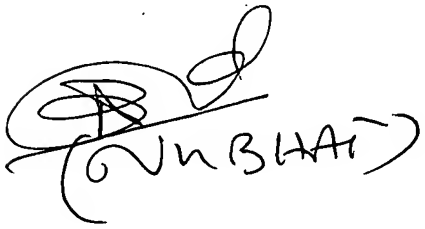
Conclusion

17. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.I

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Narayan K. Bhat Ph. D.

Examiner

Art Unit 1634